# IMPORTANT NOTICE REGARDING RADIOACTIVE MATERIALS LICENSING FEES

The Department of Health Services has determined that it is necessary to increase fees to ensure continuance of the State's radiation protection program. Fees paid are deposited into the Radiation Control Fund (RCF), which is a special fund in the state treasury created by the Legislature, to cover the costs of implementing and enforcing the Radiation Control Law, Radiologic Technology Act, Mammography Quality Assurance Act of 1992 and the laws relating to nuclear medicine technology and regulations adopted under those laws. Funds in the RCF are the only funds available to the Department for administering those laws.

The Department's fees supporting the above laws were established in 1993 and have not been adjusted except by the Legislature through Budget Acts. The last adjustment occurred in 1996. Since 1996, changes in federal and state legislative and regulatory mandates, new use of radiopharmaceuticals, and changes in radiologic technology have resulted in the Department increasing technical staff to conduct the mandated activities. This increase in staff, as well as, increases in salary, wages, benefits, operating expenses, distributed overhead and facility rental charges have resulted in increased costs not anticipated when the 1996 funding levels were established.

# **Licensing of Radioactive Materials**

Fees for licensing of radioactive materials have increased. Billing cycles for licensees remains annual.

#### Major Changes:

- New method of calculating annual fee. Method of determining fee for sealed sources is now based on total activity of all sealed sources combined.
- New fee for additional use locations.
- Application fee for new license applications. This fee is equal to the annual fee and covers the first year of the license.
- Amendment requests to increase possession limits must now include the difference between the current annual fee and the total fees required for the new requested limits.
- Technical Evaluation fee for review of sealed sources or devices (SS&D) for commercial distribution.
- Annual fee for maintenance of registry certificates for SS&D's commercially manufactured and/or distributed.
- Application for Reciprocity must include a fee based on the amount of material applicant wishes to possess while in Department jurisdiction. The fee is now calculated as specified in §30231.
- Annual Fee limit is increased to \$25,000.

Any licensee who fails to pay the annual fee by the anniversary of the effective date of the license shall immediately cease use of all sources of radiation by placing the sources in storage until such time as the annual fee and a late fee of 25 percent of the annual fee has been paid.

The amended or adopted regulatory sections addressing the above changes are as follows:

# § 30194.1. Criteria for Authorizing Multiple Locations of Use.

Criteria for authorizing more than one location of use on a specific license shall be as follows:

- (a) All locations shall be under the same business entity.
- (b) The radiation protection program required by section 20.1101 of Title 10, Code of Federal Regulations, Part 20 as incorporated by reference in section 30253 shall demonstrate that use of radioactive materials at each location shall be in accordance with this regulation.
- (c) A single location where licensing and compliance records will be maintained for Department review shall be designated.
- (d) The nature of radioactive materials use and the operations shall be the same at all locations.

Note: Authority cited: Sections 100275 and 115000, Health and Safety Code. Reference: Sections 114965, 114970, 115060, 115165, 115230 and 115235, Health and Safety Code.

## § 30194.2. Amendment Requests.

To amend an existing license, a licensee shall submit a written request to the Department containing:

- (a) The licensee's name and license number as shown on the specific license.
- (b) The nature and scope of the request.
- (c) The reasons for the request and supporting justifications including any documents relied upon.
- (d) If the request proposes to increase the maximum possession limit specified on the license, the request shall include the fee specified in section 30231(c).

Note: Authority cited: Sections 100275 and 115000, Health and Safety Code. Reference: Sections 114965, 114970, 115060, 115165, 115230 and 115235, Health and Safety Code.

### § 30230. License Fees.

(a) Except as provided in subsection (b), each applicant for a specific license pursuant to the provisions of this group shall include with the application a nonrefundable fee, which is equal to the annual fee as set forth in section 30231, and if

the specific license is granted, the application fee shall constitute the annual fee for the first year of the license.

- (b) Each applicant for a specific license for commercial distribution of sealed sources or devices containing sealed sources, who requests evaluation of the information submitted pursuant to section 30195(d)(1) and (d)(2), shall include with the application, a nonrefundable fee, which is equal to the annual fee, and a nonrefundable evaluation fee as set forth in section 30231. If the specific license is granted, the fee equal to the annual fee shall constitute the annual fee for the first year of the license.
- (c) Each licensee shall pay an annual fee, as set forth in section 30231, on or before the anniversary of the effective date of the license.
- (d) Each licensee, who applies for an amendment to a specific license that increases the maximum possession limits of the license shall include with the request submitted pursuant to section 30194.2, an additional fee for each such amendment as set forth in section 30231(c).
- (e) Each licensee authorized pursuant to section 30195(d) to commercially distribute sealed sources or devices containing sealed sources shall, in addition to the annual fee specified in section 30231(a), pay:
- (1) The evaluation fees specified in section 30231(f)(1) through (3), specific to the type of evaluation, when a request for evaluation is submitted to the Department; and
  - (2) The annual fee specified in section 30231(f)(4).
- (f) Each person authorized to conduct activities within the state pursuant to section 30225(a) shall pay a fee as specified in section 30231(e).

Note: Authority cited: Sections 100275, 115000, 115060 and 115065, Health and Safety Code. Reference: Sections 114965, 114970, 114980, 114985, 114990, 115165, 115230 and 115235, Health and Safety Code.

#### § 30231. Fee Schedule.

(a) The annual fee shall be calculated in accordance with the following formula and shall not exceed \$25,000.00 for any one license:

Annual fee (rounded to the nearest dollar) =  $A + (A \times B \times C)$ Where:

- A = [Sum of the license fee specified in subsection (b)(1), the fee for unsealed sources specified in subsection (b)(2) and the fee for sealed sources specified in subsection (b)(3)]
- B = [Number of authorized use locations minus one as specified in subsection (b)(4)]
  - C = [0.2 as specified in subsection (b)(4)].

- (b) The annual fee for each specific license shall consist of the following components:
  - (1) A fee of \$1,112.00 for each license;
- (2) A fee for the unsealed sources authorized to be possessed at any one time by the license provided such unsealed sources have a combined total strength of over 10 millicuries (mCi), as follows:

Over 10 mCi, but not over 100 mCi
Over 100 mCi, but not over 500 mCi
Over 500 mCi, but not over 1 curie (Ci)
Over 1 Ci, but not over 10 Ci \$3,814.00
Over 10 Ci, but not over 100 Ci
Over 100 Ci

(3) A fee for the sealed sources authorized to be possessed at any one time by the license provided such sealed sources have a combined total strength of over 100 mCi, as follows:

Over 100 mCi, but not over 1 Ci	\$ 636.00
Over 1 Ci, but not over 5 Ci	. \$ 1,271.00
Over 5 Ci, but not over 10 Ci	\$ 2,543.00
Over 10 Ci, but not over 100 Ci	\$ 3,814.00
Over 100 Ci, but not over 1,000 Ci	. \$ 5,085.00
Over 1,000 Ci	. \$ 6,357.00; and

- (4) A fee for each location of use greater than one, authorized in a specific license pursuant to section 30194.1, which is determined by multiplying the number of authorized use locations minus one by the sum of the values of subsections (b)(1) through (3) and by 0.2.
- (c) The amount of additional fee required pursuant section 30230(d), except as limited by this section, shall be the difference between the current annual fee and the total annual fees required for the new limits requested.
- (d) Any licensee who fails to pay the annual fee by the anniversary of the effective date of the license shall immediately cease use of all sources of radiation by placing the sources in storage until such time as the annual fee and a late fee of 25 percent of the annual fee has been paid.
- (e) The fee for persons authorized to operate under section 30225(a) shall be equal to the annual fee as specified in subsection (a) for the combined total strength of radioactive material that will be possessed while in this state. The fees shall be effective for the period in which reciprocity is granted under section 30225.
- (f) The fees required by subsections (b) and (e) of section 30230 shall be as follows:
  - (1) \$4,270.00 for evaluation of each device and sealed source;
  - (2) \$3,270.00 for evaluation of each device only;
  - (3) \$1,000.00 for evaluation of each sealed source only; and

- (4) \$400.00, annually, for each registry certificate maintained by the Department indicating that the sealed source or device is commercially manufactured and/or distributed and includes evaluations of modifications of the source or device identified on the certificate.
  - (g) Fees required by this section shall be nonrefundable.

Note: Authority cited: Sections 100275, 115000, 115060 and 115065, Health and Safety Code. Reference: Sections 114965, 114970, 114980, 114985, 115165, 115230 and 115235, Health and Safety Code.